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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,767	01/10/2002	Wolf B. Frommer	056100-5039-US	4393

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,767	FROMMER ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25,26,28-38,40-42,44-48 and 56-67* is/are pending in the application.

4a) Of the above claim(s) *35,36,40 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,25,26,28-34,37,38,41,42,45-48 and 56-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/17/05 in reply to the Office action of 07/15/05 has been entered. Claims 23, 26, and 61 are amended. Claims 66-67 are added. Therefore, claims 23, 25-26, 28-38, 40-42, 44-48, and 56-67 are pending. This application contains claims 35-36, 40 and 44 drawn to an invention nonelected with traverse in the response of 08/23/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claims 23, 25-26, 28-34, 37-38, 41-42, 45-48 and 56-67 are under consideration.

Claim Objections

Claim 26 is objected to for failing to further limit parent claim 23 because the nucleic acid of claim 26 is broader in scope than the nucleic acid of claim 23.

Claims 45-46 are objected to for failing to further limit parent claim 26. A nucleic acid fragment that is at least ten contiguous bases is broader in scope than a nucleic acid fragment that is 50 or 200 (non-contiguous) nucleotides.

Claim Rejections - 35 USC § 112

Claims 23, 25-26, 28-34, 37-38, 41-42, 45-48 and 56-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence encoding SEQ ID NO: 8, the nucleic acid of SEQ ID NO: 1, host cells/plants/parts/seed comprising said nucleic acid sequence, and a method for transforming a plant/cell with said nucleic acid sequence, does not reasonably provide enablement for a nucleic acid that hybridizes to a nucleic acid encoding SEQ ID NO: 8 and encoding a protein with nuclear base transporter activity, a nucleic acid encoding a polypeptide having at least 40% identity to SEQ ID NO: 8 and having nuclear base transporter activity, a nucleic acid fragment thereof with ten contiguous bases having inhibition activity, or 50 or 200 nucleotides , host cells/plants/parts comprising said nucleic acid sequence, and a method that employs said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office actions of 07/15/05. Applicant's arguments filed 10/17/05 have been considered but are not deemed persuasive.

Applicant asserts that amended claim 23 recites one of the plant nuclear base transporter nucleic acid sequence disclosed in the specification and sequences that hybridize thereof or encode protein having a high level of sequence identity and having nuclear base transporter activity. Applicant cites Burkle et al (The Plant Journal (2003) to show that SEQ ID NO: 2 disclosed in the instant specification encodes a nuclear

base transporter protein with at least 40% sequence identity to SEQ ID NO: 8 (response, pp. 11-13).

These are not persuasive because the scope of claim 23 as amended is not supported by an enabling disclosure for the reasons set forth in the last Office action. Claim 23 is not limited to the nucleic acids of SEQ ID NO: 1 or 2, but encompasses nucleic acid from any plant source that hybridizes to a nucleic acid encoding SEQ ID NO: 8 and still encoding a polypeptide or protein having nuclear transporter protein activity. The hybridization conditions as recited in the claim is not predictable to yield nucleic acids that are functionally related to a nucleic acid encoding SEQ ID NO: 8. In addition, neither the instant specification nor the prior art provides evidence that suggests the hybridizing property of a nucleic acid can be used to predict the biological function of the nucleic acid. Claim 23 recites a nucleic acid encoding a polypeptide or protein that lack up to 60% identity with SEQ ID NO: 8. Because Applicant has not provided guidance which region in the full length sequence of SEQ ID NO: 1 or 2 is required to encode a functional protein, one would have to proceed trial and error experimentation to determine which of the multitude of nucleic acids encoding proteins having as low as 40% sequence identity (60% lack of identity) would retain the desired nuclear transporter pro activity.

Applicant also argues that nucleic acids of claim 26 (and dependents 45 and 46) as amended recite nucleic acid fragments that inhibit expression of a nuclear base transporter, and that it is well within the level of one of ordinary skill in the art to design fragments of the disclosed sequences having the recited lengths of ten, 50 and 200

nucleotides that inhibit protein activity when expressed in the antisense orientation. Applicant further argues that other disclosed sequences encode proteins with at least 40% identity are predicted to encode proteins having similar function (response, p. 14).

These are not found persuasive because the specification does not provide guidance for a nucleic acid comprising 10 consecutive bases or 50 or 200 nucleotides of the disclosed sequences that inhibits expression of a nuclear base transporter in a transgenic plant. The enabling disclosure is limited to the antisense sequences of SEQ ID NO: 1 and 2. The specification provides no more than an invitation to experiment as to whether the claimed fragments of 10 consecutive bases or 50 or 200 nucleotides would inhibit expression of a nuclear base transporter, such experimentation would require undue and excessive experimentation. Applicant discloses no property that relates SEQ ID NO: 3-7 and 10 to nuclear base transport activity, and no evidence to support the conclusion that other Arabidopsis sequences would also possess functional property similar to that of SEQ ID NO: 1 or 2.

Applicant further argues that methods of modifying a given gene to contain multiple mutations have been routine in the art. Applicant cites Pjura et al (Protein Science, 1993, 2:2217-2225); Uppaluri et al (Mol. Cell. Biol., 1995, pp. 1499-1512); and Kim et al (J. Biol. Chem. 1996, 271(9): 4872-78), to support this position.

These are not persuasive because none of the cited references teach about mutagenesis of a nuclear transporter protein/gene or provide any relationship to a the nuclear transporter protein of the instant invention. Pjura et al teach identification of a single-site mutant T4 lysozyme, functionally and structurally well-characterized mutants.

Uppaluri et al teach randam mutations of thyroid hormone receptor, a receptor with well-characterized functional domains. Kim et al teach identification of active mutants of human immunodeficiency virus (HIV) reverse transcriptase, which has no known relationship with a plant nuclear transporter protein.

In Genentech Inc v. Novo Nordisk A/S (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....[w]hen there is no disclosure of any specific starting material or conditions under which a process can be carried out, undue experimentation is required...." In this case, Applicant is expecting others to identify functional domains of a nuclear transporter, and where and how to modify the disclosed sequences to produce nucleic acids having the structural properties as recited in the claims (encoding proteins with 40% identity to SEQ ID NO: 8; having hybridizing property as recited in the claims; and fragments with as few as 10 contiguous bases, or with 50 or 200 nucleotides having inhibition activity). Applicant is also expecting others to determine if the nucleic acids encode functional nuclear transporter when expressed in a transgenic plant. Under the guidelines set forth in *Genentech*, this constitutes under experimentation.

See also *in re Fischer, 166 USPQ 19 24 (CCPA 1970)* where the court required that the scope of the claims must bear a reasonable correlation with the scope of the

enablement. In this case, the enablement is limited to SEQ ID NO: 1and 2 and the antisense of SEQ ID NO: 1 and 2.

Therefore, for all the reasons stated above and in the last Office action, the claimed invention is not enabled throughout the broad scope. Therefore, the rejection is maintained.

Written Description

Claims 23, 25-26, 28-34, 37-38, 41-42, 45-48 and 56-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office actions of 07/15/05. Applicant's arguments filed 10/17/05 have been fully considered but are not deemed persuasive.

Applicant argues that a nucleic acid encoding proteins having at least 40% sequence identity with SEQ ID NO: 8 and having nuclear transporter protein activity has been isolated by homology analysis. Applicant refers to SEQ ID NO: 2 of the instant specification and PUP2 gene of Burkle et al (The Plant Journal (2003) 34, 13-26) encoding a protein having 58% sequence identity to SEQ ID NO: 8 (response, pp. 16-17).

These are not persuasive because Applicant's argument is not commensurate in scope of the claims. Firstly, SEQ ID NO: 2 is not included in the instant rejection. Secondly, PUP1 (SEQ ID NO: 1) PUP2 (SEQ ID NO: 2) gene of Burkle et al are both

from Arabidopsis and share 64% sequence identity at the amino acid level (see page 17, paragraph bridging columns 1 and 2 of Burkle et al). Thirdly, the rejected claims are drawn to a nucleic acid from any source encoding a protein having as low as 40% sequence identity to SEQ ID NO: 8; the composition and structure of such nucleic acid are not described in the specification or in Burkle (2003). In addition, a substantial variation in structures and function is expected among nucleic acids that share 10 contiguous bases or 50 or 200 nucleotides in length. Applicant has neither described a representative number of nucleic acids falling within the scope of the genus nor disclosed structural features common to members of the genus, which features constitute a substantial portion of the genus, as stated in the last Office action.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention is not adequately described. Therefore, the rejection is maintained.

Conclusion

The claims are deemed free of the prior art of record.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

01/09/06
Mai

MEDINA A. IBRAHIM
PATENT EXAMINER